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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/974,712	10/10/2001	Carl Johan Friddle	LEX-0251-USA	7859

24231 7590 05/16/2003

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EXAMINER
LANDSMAN, ROBERT S

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 05/16/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/974,712	FRIDDLE ET AL.	
	Examiner	Art Unit	
	Robert Landsman	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 April 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5* is/are pending in the application.

4a) Of the above claim(s) *4* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *9* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Formal Matters

A. Amendment A, filed 4/23/03, has been entered into the record.

B. The Information Disclosure Statement, filed 11/26/02, has been entered into the record.

C. Claims 1-4 are pending in the application. In Amendment A, Applicants added claim 5. Claim 4 has previously been withdrawn as being drawn to a non-elected invention. Therefore, Claims 1-5 are pending and claims 1-3 and 5 are the subject of this Office Action.

D. All Statutes under 35 USC not found in this Office Action can be found, cited in full, in a previous Office Action.

2. Information Disclosure Statement

A. Reference CP on the Form PTO-1449, filed 11/26/02, has been lined through since no submission date for this deposit has been cited.

B. The reference to the International search report for Application No. PCT/US01/31900 on the Form PTO-1449 (no reference number has been provided). However, this would be considered reference CQ), has been lined through since reference to the International Search Report itself is not a proper citation.

3. Specification

A. The objection to the title has been overcome in view of Applicants' submission of a new title which more closely described the claimed invention.

B. The objection to the abstract has been overcome in view of Applicants' submission of a more concise abstract which states that the invention relates to ion channel proteins.

4. Claim Rejections - 35 USC § 101

A. Claims 1-3 remain rejected and new claim 5 is also rejected under 35 USC 101 for the reasons already of record on pages 3-5 of the Office Action dated 12/17/02. Applicants argue that the presently claimed sequence is clearly referred to as an ion channel protein in the title and specification. This argument has been considered, but is not deemed persuasive. Respectfully, though Applicants suggest that

the sequence(s) of the present invention encodes ion channel proteins, this is speculative. There is no data to support this assertion. It cannot be concluded that the protein of the present invention is an ion channel simply because the specification states that it is believed to be an ion channel. Similarly, the Examiner was only referring to the protein of the present invention as an ion channel simply for ease of discussion in the Office Action of 12/17/02.

Applicants argue that "an invention is useful under section 101 if it is capable of providing some identifiable benefit" and that "any utility of the claimed compounds is sufficient to satisfy 35 USC 101." However, as stated under the current utility guidelines (published 1/5/01, 66 FR 1092), the claimed invention needs to be supported by a specific and substantial asserted utility, or a well-established utility. However, no specific, or substantial benefit has been identified. The fact that these proteins "mediate or facilitate the passage of materials across the lipid bilayer" is not a utility specific to the protein of the present invention, as this is the general the function of voltage-gated ion channel proteins as a whole. Applicants have not taught what the specific function is of the protein encoded for by the nucleic acid molecules of the present invention, nor have Applicants identified a substantial role of this protein; for example, how this specific ion channel protein can be used, or with what diseases this specific protein is associated.

Furthermore, Applicants argue that Brenner v. Manson is not analogous to the present situation since an activity, such as an anticancer activity, is distinct from a term (i.e. ion channel) that defines a molecular function. Applicants argue that ion channels have a well-known biological role and that this description is more specific than a general "activity." However, the Examiner maintains that while these examples are not identical, they are, in fact, analogous. If the artisan were to consider "ion channel activity" to be analogous to "anticancer activity," as was intended in this analogy, then it can be seen how, simply because one protein or compound was known to have activity, this does not confer activity to other homologous proteins or compounds. Furthermore, the Examiner does not understand how these terms differ, i.e. how one is more general than the other. "Ion channel activity" is just as general or as specific as "anticancer activity." Both of these terms define a specific function (specific proteins which transport specific ions vs. specific drugs which affect specific cancer cells) as well as a general function (ion channels and the general concept of transporting ions vs. any drug which affects any cancer). Therefore, this situation, as well as the terms "ion channel activity" and "anticancer activity" are sufficiently analogous to be pertinent to this rejection. Even if, *arguendo*, these situations were not analogous, homology alone is not a sufficient basis for a determination of utility, as discussed throughout this rejection.

Applicants further cite *In re Brana*, their major argument being that "further research does not preclude a finding that the invention has utility" and that "further research and development" is (may be) necessary. However, In re Brana, as stated by Applicants, is concerned with the utility of *pharmaceutical compositions* whereas the present invention is concerned with ion channel *proteins*. In using Applicants' own logic, as seen in the above paragraph regarding Applicants' discussion of the relevance of Brenner v. Manson to the present invention, compounds (and pharmaceutical compositions) are not analogous to ion channel proteins. Applicants make no mention in their arguments of Brana that the compounds, themselves, to be used in the pharmaceutical compositions do not have utility. Applicants only state that Brana is concerned with the *pharmaceutical compositions* comprising these compounds. Applicants discuss the significance of the FDA and Phase II testing regarding Brana. However, these issues are not relevant in this situation. If Applicants were claiming that the protein of the present invention, or nucleic acids encoding this protein, could be used in pharmaceutical compositions, that would be analogous. However, the proteins themselves would first need to possess utility in order for the pharmaceutical composition to possess utility. Since the proteins of the present invention do not possess utility, any comparison to Brana is, respectfully, irrelevant.

Furthermore, Applicants show that GenBank Accession No. AF315818 encodes a voltage-gated potassium channel which, after the first 38 bases, is 99.9% identical to that of the present invention and that the reference citing this nucleic acid and protein (Bardien-Kruger et al.) teaches that this protein is believed to be involved in specific diseases, such as PFHBI. Applicants, therefore, argue that one skilled in the art would recognize the utility of the protein of Bardien-Kruger et al. as a utility of the protein of the present invention. However, Applicants did not disclose the utility of the ion channel protein of the present invention at the time of filing. Utility has to have been present *at the time the invention was made (filed)*. Without knowing which cardiac disorders, or any other disorders, were associated with the protein of the present invention, the use of this protein, or encoding nucleic acid molecules, was not known at the time the invention was made. Post-filing references can only be used to support an assertion made in the specification at the time of filing. This is not the case here. As stated on page 4 of the Office Action dated 12/17/02, a patent is not a hunting license. This same statement can be made with regard to Applicants' argument using *In re Angstadt and Griffin*. Applicants state that "the need for some experimentation does not render the claimed invention unpatentable." However, this amount of experimentation required to practice the claimed invention is "undue" since, as discussed throughout this rejection, the only information disclosed in the instant specification is that the protein is believed to be an ion channel protein, with no further support of utility. Again, a patent is not a hunting license.

Applicants additionally argue that the references cited by the Examiner (Skolnick, Bork, Doerks, Smith, Brenner and Bork), if anything, support Applicants' assertion that homology can be used to predict the function of a novel protein, or encoding nucleic acid. All of Applicants' points regarding these references have been considered. Taken as a whole, these references show that prediction of novel proteins based on known homologous proteins is, at best, speculative. In addition, the issue raised by the Examiner is not that protein structure is not predictive of function, but that the standard in the art is that it is only suggestive, and needs to be confirmed by actual experimental results, which has not been done in the present situation. Therefore, homology alone is not a sufficient basis to conclude utility.

Furthermore, Applicants argue that the nucleic acid molecules of the present invention can be used in gene (DNA) chips and that these chips have substantial industrial utility. They also argue that the protein of the present invention is a G protein-coupled receptor, and, therefore, is a potential drug target and specific marker of the human genome, for chromosome mapping, or for defining exon-splice junctions. Applicants also state that "the practical scientific value of expressed, spliced, and polyadenylated mRNA sequences is readily apparent to those skilled in the...arts." However, none of these assertions are specific to the protein of the present invention, or its encoding nucleic acids. Any nucleic acid can be used in gene chip technology, or as a marker for a specific location on the human genome and the like. Similarly, hundreds of G protein-coupled receptors are known in the art and are used as drug targets. Again, this is not specific to the protein of the present invention. As made in a similar statement above, the fact that this nucleic acid molecule maps to chromosome 19q13.3 was not disclosed at the time of filing, nor does this knowledge provide any specific or substantial information regarding this chromosome, or the nucleic acid molecule. The argument that the nucleic acid of the present invention is part human genome project is also not persuasive since, while the human genome project as a whole may be useful, a single nucleic acid molecule, such as the one disclosed in this invention, by itself, is not.

Finally, Applicants bring to the Examiner's attention numerous patents on polynucleotide sequences that have not been directly shown to be associated with the function of the protein set forth in the specification and which claim, for example, polynucleotide fragments. These arguments have been considered, but are not persuasive. First, this application was properly examined under, and is consistent with, the current utility guidelines, published 1/5/01, 66 FR 1092. Furthermore, all U.S. Patent are presumed valid, or would not have issued as U.S. Patents. Since the polynucleotides in these patents have utility, fragments of these polynucleotides have utility. It is believed that all pertinent arguments have been addressed.

Therefore, since the nucleic acid molecule of the invention does not possess a specific, substantial and credible asserted utility or a well established utility, the claimed expression vector and cells also do not possess utility.

5. Claim Rejections - 35 USC § 112, first paragraph - enablement

A. Claims 1-3 remain rejected and new claim 5 is also rejected under 35 USC 112, first paragraph, for the reasons already of record on page 6 of the Office Action dated 12/17/02 as well as for the reasons given in the above rejection under 35 USC 101. Applicants argue that the claimed invention is enabled because it has utility as argued previously. Applicants' arguments have been fully considered, but are not found to be persuasive for the reasons discussed above.

6. Claim Rejections - 35 USC § 112, second paragraph

A. The rejection of claim 2 under 35 USC 112, second paragraph, has been withdrawn in view of Applicants' amendment to the claim to recite hybridization conditions.

7. Conclusion

A. No claim is allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (703) 306-3407. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Fax draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert Landsman, Ph.D.
Patent Examiner
Group 1600
May 15, 2003

ROBERT LANDSMAN
PATENT EXAMINER